

FORM PTO-1390 (REV 5-93)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER <div style="text-align: center; font-weight: bold; font-size: 1.2em;">SG 98519</div>	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <div style="text-align: center; font-weight: bold; font-size: 1.5em;">09/171889</div>	
INTERNATIONAL APPLICATION NO. PCT/SE97/00855		INTERNATIONAL FILING DATE 26 May 1997 (26.05.97)		PRIORITY DATE CLAIMED 24 May 1996 (24.05.96)	
TITLE OF INVENTION VOICE PROSTHESIS					
APPLICANT(S) FOR DO/EO/US PERSSON, Jan-Ove					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 					
Items 11. to 16. below concern other document(s) or information included:					
<ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.23 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 14. <input type="checkbox"/> A substitute specification. 15. <input type="checkbox"/> A change of power of attorney and/or address letter. 16. <input checked="" type="checkbox"/> Other items or information: <ol style="list-style-type: none"> a. International Search Report (attached to the International Application) b. International Preliminary Examination Report 					

Voice Prosthesis

The invention relates to a voice prosthesis to be mounted in a fistula between trachea and esophagus, comprising a spool-shaped element having a throughpassage and a valve mechanism controlling the connection through said passage, said valve mechanism having sealing surfaces which can be pressed against each other.

When a person's larynx has been removed by surgery due to pathological changes in the throat trachea is sutured to an opening in the throat (tracheostoma). By the surgery the person has lost the ability to speak, and in order to restore this ability a method has been applied for several years, in a voice prosthesis of the kind referred to above is mounted in a fistula, i.e. a passage between trachea and esophagus. At speech the tracheostoma is occluded by sealing the same either by the patient placing the fingers against the tracheostoma or by the tracheostoma being closed by an in connection therewith provided stoma valve. Then, the expiration air is pressed from the lungs through the voice prosthesis into esophagus where the mucous membranes of the throat are brought into vibration and speech is produced as a consequence thereof. Several voice prosthesis are described in US-A-4 911 716, US-A-4 435 853, US-A-4 820 304, and DD-A1-275 183. The voice prosthesis is fixed in the fistula by means of two flanges on the spool-shaped element or by means of a flange and ribbons. The spool-shaped element can be cylindrical or oval and preferably it is made of silicon rubber. All existing voice prostheses have in common that they provide a check valve function, which means that the valve mechanism normally is closed but opens when air is pressed from trachea via the valve to esophagus. The valve mechanism is maintained in the closed position by spring bias which in most cases is maintained by elasticity of the material from which the voice prosthesis is made.

When existing voice prostheses are mounted in the fistula the function is acceptable initially but they have a non-acceptably short life ranging from a week up to two years. There are two reasons for this short life, viz.

5 1) Growth of fungus, candida, will cover the sealing surfaces of the valve mechanism, which causes leakage at the intake of beverages and is the primary reason for exchange of the voice prosthesis.

10 2) Fatigue of the spring bias (the material of the voice prosthesis) so that the valve as a consequence thereof will be partly open in the normal position causing leakage through the voice prosthesis.

15 A further drawback adds to these drawbacks viz. that the spring bias which shall maintain the valve mechanism closed in the normal position increases with the opening movement of the valve mechanism so that a considerably increased air resistance will be obtained as a consequence
20 thereof at increased air flow, which means that the patient will be restrained from producing a more powerful speech or in any case cannot produce such speech without great effort, which makes the speech strenuous.

25 The purpose of the present invention is to overcome the drawbacks mentioned above, and for this purpose the voice prosthesis of the kind referred to above has obtained the characterising features according to claim 1.

30 In existing voice prostheses the valve mechanism opens relatively quickly and preferably at low pressure when air with the stoma closed is pressed against the valve mechanism. Then, when the air flow is increased at speech the flow resistance will quickly be increased as mentioned above. In a voice prosthesis in accordance with the present invention a slightly higher pressure is initially required
35 at speech but once the valve mechanism has opened the clos-

ing force will be considerably lower at greater air flow and thus also the flow resistance will be lower than in existing voice prostheses.

It is known per se to provide a valve mechanism with a permanent magnet function in order to maintain the valve mechanism in closed condition. Thus, there is disclosed in WO 93/11820 a cough valve having a valve flap which is kept in closed position against a seat by the force of a permanent magnet said force acting between the valve flap and the seat, in order to be opened at arising high overpressure in trachea such as at an attack of coughing. It is thus the question of a pure safety valve wherein the permanent magnet function is utilized for a completely other purpose than for overcoming the drawbacks connected with existing voice prostheses, which have been discussed above and which are not at all mentioned in WO 93/11820.

As mentioned above the growth of candida on the sealing surfaces of the voice prosthesis is the main reason for the necessity of exchanging the voice prosthesis. It is well known that the candida fungus affects silicon rubber which is the material almost exclusively used in voice prostheses, and above all at such places which are in contact with the mucous membranes in the throat. When the magnet function is utilized in order to maintain the voice prosthesis in closed position as in the voice prosthesis according to the present invention the portions sealing against each other in the valve mechanism can consist of or be coated with a hard candida resistant material, for example PVDE, polypropylene or polyethylene, which, however, in existing voice prostheses rather quickly would result in beginning leakage at beginning fatigue of the silicon rubber the elasticity of which produces the closing force, because an increased compression force is required in order to seal between two hard surfaces than between two soft surfaces. A reduced compression force cannot push away food

residues, if any, adhering to the sealing surfaces so that also for this reason leakage can arise in the voice prosthesis. The invention thus provides a new possibility of overcoming the problem of candida growth in voice prostheses.

The invention will be described in more detail below reference being made to the accompanying drawings in which FIGS. 1 to 9 are axial cross-sectional views of different embodiments of the voice prosthesis according to the invention.

In the embodiment according to FIG. 1 the voice prosthesis comprises a spool-shaped element 10 which can be made of silicon rubber or another elastic tissue compatible material and forms an axial through passage 11. The spool-shaped element has at one end thereof, the distal end, an outside flange 12 which is intended to engage the inside surface of esophagus, and at the other end, the proximal end, an outside flange 13 which is intended to engage the inside surface of trachea. Said latter flange can be replaced by ribbons for attaching the voice prosthesis with flange 12 engaging the inside surface of esophagus. The spool-shaped element can be circular or oval in cross-section. In passage 11 a rigid lining 14 of a candida resistant material is provided, which forms an annular valve seat 15 and a shield 16 extending outwards from the seat at the distal end of passage 11 where flange 12 is located. By means of a joint 17 formed as a bending element a valve flap 18 is articulately connected to the spool-shaped element said element and the valve flap as well as the bending element provided therebetween as a web forming a unit made of one and the same material. The bending element can be considerably thinner in the present case than in corresponding prior art embodiments of the voice prosthesis of the type disclosed in FIG. 1 in order to minimize the flow resistance in the voice prosthesis. The valve flap at the

surface thereof to be engaged with the seat is provided with a plate 19 of candida resistant material or is coated with such a material.

A permanent magnet 20 is provided in the valve flap and is connected with the flap by gluing or by being moulded into the material at injection moulding of the valve flap. Seat 15 should be made of a magnetically attractable material so that the valve flap by magnetic force normally is held in closed position sealingly engaging the seat but can be lifted momentarily from the seat by an overpressure in trachea overcoming the magnet force. Lining 14 or at least that part thereof which forms seat 15 preferably consists of magnetic stainless steel. In a modification of the embodiment shown the magnet or several magnets are provided in seat 15 and a plate 19 is made of a magnetically attractable material such as magnetic stainless steel. Shield 16 protects the valve mechanism against candida attack. In order that the permanent magnet 20 shall be protected against corrosion it can be coated with a corrosion resistant material.

FIG. 2 discloses a modification of the embodiment in FIG. 3 wherein the seat comprises a flat ring 21. In this case valve flap 18 as well as seat ring 21 are provided with a permanent magnet 20 and 20', respectively. Alternatively, only either plate 19 on the valve flap or seat ring 21 is provided with magnet and the seat ring and the plate, respectively, is made of a magnetically attractable material.

The embodiment shown in FIG. 3 principally is constructed in the same way as the embodiment in FIG. 1 but valve flap 18 has been replaced by a valve element formed as a ball 22 which is supported by a strip 23 made integral with flange 12 and allowing ball 22 to be lifted from seat 15 under elastic yielding. Ball 22 is provided with one or more permanent magnets 20 in order to be held by magnet

force in engagement with seat 15 consisting of a magnetically attractable material. Alternatively ball 22 in its entirety can comprise a permanent magnet, or one or more permanent magnets can be provided in the seat to attract
5 ball 22 which in that case is made in its entirety of a magnetically attractable material.

The embodiment in FIG. 4 is slightly different from the embodiment previously described because the valve mechanism is of the type "duck bill". It is formed by a
10 slotted extension 10' of the spool-shaped element 10, projecting from flange 12. The slot is indicated at 24 and is defined by surfaces having a coating 25 of candida resistant material. The two halves of extension 10' formed by the slot are mutually attracted by two permanent magnets 20
15 one on each of said two halves, in order that the slot, i.e. the valve mechanism shall be kept closed. At overpressure in trachea acting in passage 11 the magnet force will be overcome and slot 24 will be opened under elastic separation of the two halves of extension 10' so that a connection through passage 11 will be established. Instead of the
20 two halves of extension 10' being provided with a magnet, only one of said halves can have a magnet and the other one can have a block of magnetically attractable material co-operating with the magnet.

25 In the embodiment according to FIG. 5 lining 14 made of candida resistant material forms seat 15 in passage 11 said seat forming radial arms 26 supporting a guide 27 for a stem 28 on a disk valve 29 co-operating with seat 15. Disc valve 29 is provided with one or more permanent magnets 20, and for co-operation with the magnet or the magnets, respectively, guide 27 is partly made of a magnetically attractable material 30 so that disc valve 29 is kept
30 in engagement with seat 15 by magnet force. At overpressure in passage 11 which acts against disc valve 29 this is
35 lifted from seat 15 the magnet force being overcome, so

that a connection is established through passage 11. In a modification of this embodiment the guide is provided with a permanent magnet and the disc valve is provided with or is made of a magnetically attractable material. Preferably,
5 disc valve is made of a candida resistant material in its entirety.

FIG. 6 discloses an embodiment in accordance with FIG. 1 wherein the permanent magnet, however, is replaced by an electromagnet. A wire winding 31 is embedded into
10 lining 14 and has connection wires 32 for connection of the winding to an electric power source. The lining and thus the seat in this case should consist of a magnetizable material to be magnetized at energization and thus attract plate 19 on valve flap 18 said plate consisting of a mag-
15 netically attractable material.

In FIG. 7 the embodiment of the voice prosthesis according to the invention presently preferred is disclosed said embodiment being a modification of the embodiment in FIG. 1 as is the embodiment in FIG. 2. In this embodiment
20 the voice prosthesis comprises a spool-shaped element 10 of silicon rubber having a distal outside flange 12 and a proximal outside flange 13 said latter flange being shown with a "tail" or strap 33 (fragmentarily shown) having a suitable length. This strap can be used in handling the
25 voice prosthesis when it shall be mounted in or demounted from the fistula and also can serve as anchoring means for anchoring the voice prosthesis on an insertion instrument. The spool-shaped element in this embodiment forms an obliquely bevelled extension 34 at the distal end. When the
30 voice prosthesis is positioned in the fistula said portion extends into esophagus and prevents liquid and food passing down through esophagus from entering passage 11 in the spool-shaped element and from disturbing the function of the voice prosthesis. A lining 14 of a candida resistant
35 and magnetically attractable material, e.g. magnetic stain-

less steel is inserted into the passage, and said lining at the distal end forms the annular seat 15 of the voice prosthesis. The lining can be attached by vulcanization or gluing to the spool-shaped element.

5 The valve flap 18 of the voice prosthesis, which co-operates with seat 15 consists of hard plastics and forms a cavity 35 in which a permanent magnet 20 is located and is retained therein by means of a glue layer 36 in the cavity, extending over the magnet. Valve flap 18 is articulately
10 connected with the spool-shaped element 10 by means of a portion 37 which is injection moulded integrally with the spool-shaped element in another cavity 38 in valve flap 18 and at a web 17 provided as a joint connects to the rest of element 10, a pin 39 on the valve flap being surrounded by
15 portion 37 for locking said portion on the valve flap.

In this embodiment the lining can be made of plastics and can have at the distal end thereof a permanent magnet moulded or glued into the lining. By this arrangement the risk of the lining eventually being magnetized by magnet 20
20 is avoided. By such magnetization the magnetic retainment of the valve flap in closed position may be uncontrollably strong and may require an opening pressure which is too high.

In the embodiment according to FIG. 8 valve flap 18
25 consisting of hard plastics with a magnet 20 moulded thereinto is connected by means of a pivot 41 with a hinge flange 42 of hard plastics which is attached by vulcanization to the spool-shaped element and is kept engaged with the outside surface of lining 14 which can consist of a
30 magnetically attractable material such as stainless steel, or can be made of plastics with a built-in permanent magnet for co-operation with magnet 20.

In FIG. 9 hinge flange 42 is made as an integral portion of a ring 43 of hard plastics, which forms seat 15 and
35 is attached to the spool-shaped element 10 by vulcanization

and which engages lining 14 inserted into said element.
Also in this case the lining can consist of stainless steel
or plastics with a built-in permanent magnet in order to
keep the valve flap against seat 15 in co-operation with
5 magnet 20 moulded into the valve flap. The spool-shaped
element in this case has an obliquely bevelled extension 34
with a permanent magnet 44 moulded thereinto, which has
such polarity in relation to magnet 20 that it repels this
magnet and thus the flap so that this cannot be left in
10 open position.

Lining 14 in the several embodiments of the voice
prosthesis according to the invention can be attached to he
spool-shaped element 10 by vulcanization or gluing, but it
is also possible to provide as an alternative or complement
15 a mechanical attachment by the lining being pushed into
passage 11 and under elastic yielding of the spool-shaped
element snaps into positive engagement with said element at
shoulders on the outside surface of the lining and inside
the passage.

20 Instead of the lining being made of stainless steel
in the embodiments according to FIGS. 1 and 3 and 7 to 9 it
can be made of hard plastics with one or more permanent
magnets moulded thereinto for co-operation with the magnet
in the valve flap.

CLAIMS

1. Voice prosthesis to be mounted in a fistula
between trachea and esophagus, comprising a spool-shaped
element having a through passage and a valve mechanism con-
trolling the connection through said passage, said valve
mechanism having sealing surfaces which can be pressed
against each other, c h a r a c t e r i z e d by means for
providing a magnet force acting between the sealing sur-
faces to keep said surfaces pressed against each other in
the closed position of the valve mechanism.

2. Voice prosthesis according to claim 1,
c h a r a c t e r i z e d in that said means comprises a
magnet on one of two elements moveable in relation to each
other, which form said sealing surfaces, and a magnet or a
magnetically attractable material on the other element.

3. Voice prosthesis according to claim 2,
c h a r a c t e r i z e d in that the magnet or each mag-
net, respectively, comprises a permanent magnet.

4. Voice prosthesis according to claim 2,
c h a r a c t e r i z e d in that the magnet or each mag-
net, respectively, comprises an electromagnet.

5. Voice prosthesis according to any of claims 2 to
4, c h a r a c t e r i z e d in that the magnet or the
magnets, respectively, are attached by gluing.

6. Voice prosthesis according to any of claims 2 to
4, c h a r a c t e r i z e d in that the magnet or the
magnets, respectively, are attached by moulding.

7. Voice prosthesis according to any of claims 2 to
6, c h a r a c t e r i z e d in that the magnet or the

magnets, respectively, are coated with a surface layer of corrosion resistant material.

8. Voice prosthesis according to any of claims 1 to
5 7, c h a r a c t e r i z e d in that at least one of the sealing surfaces consists of a candida resistant material.

9. Voice prosthesis according to claim 8,
c h a r a c t e r i z e d in that the candida resistant
10 material forms one sealing surface in the shape of a valve seat and is extended axially on at least one side of the seat as a lining in the passage through the spool-shaped element.

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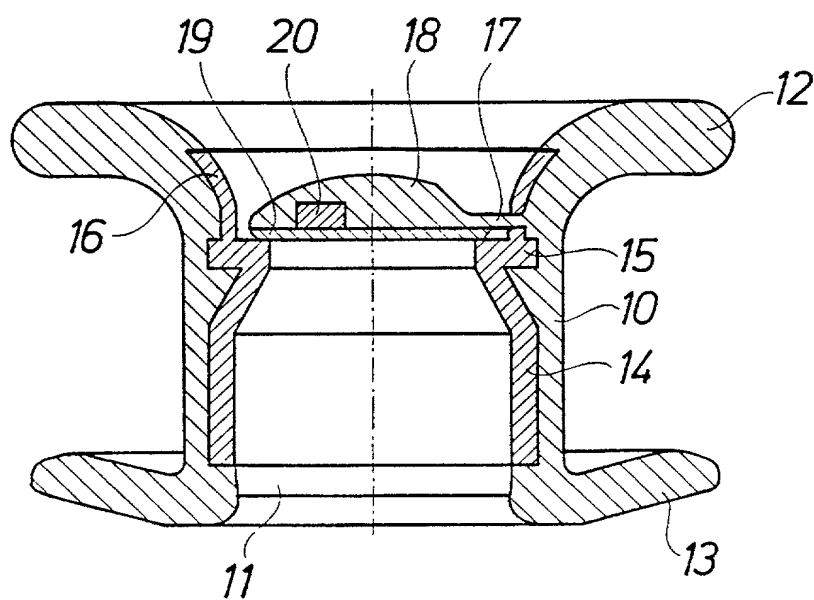


FIG. 1

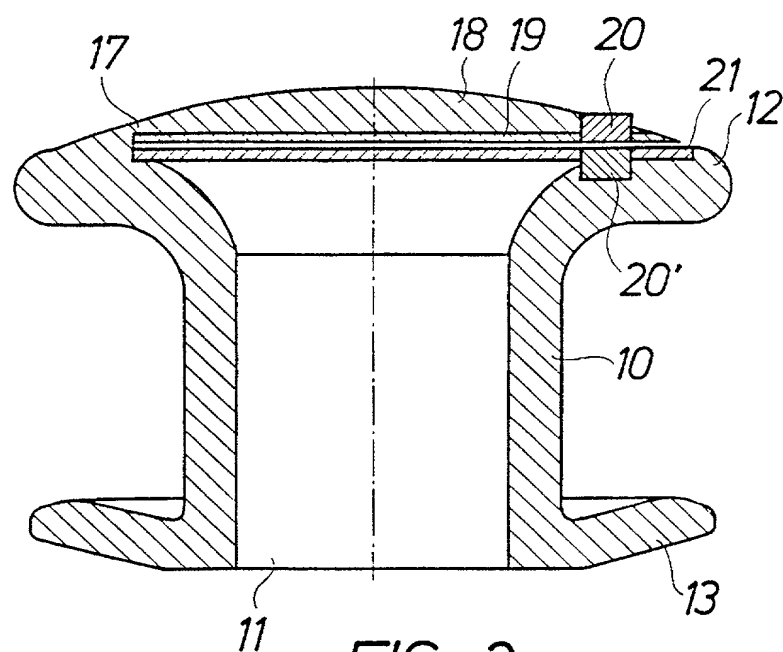


FIG. 2

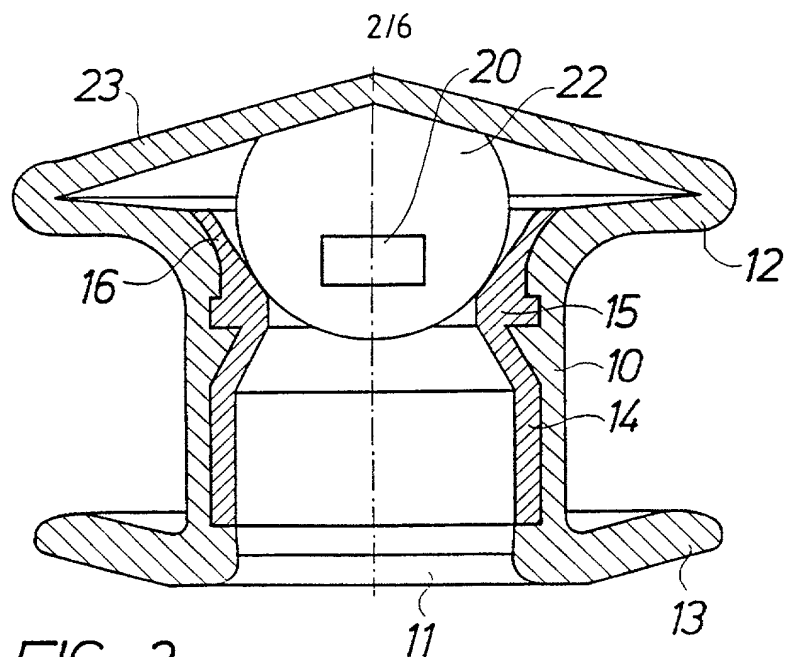


FIG. 3

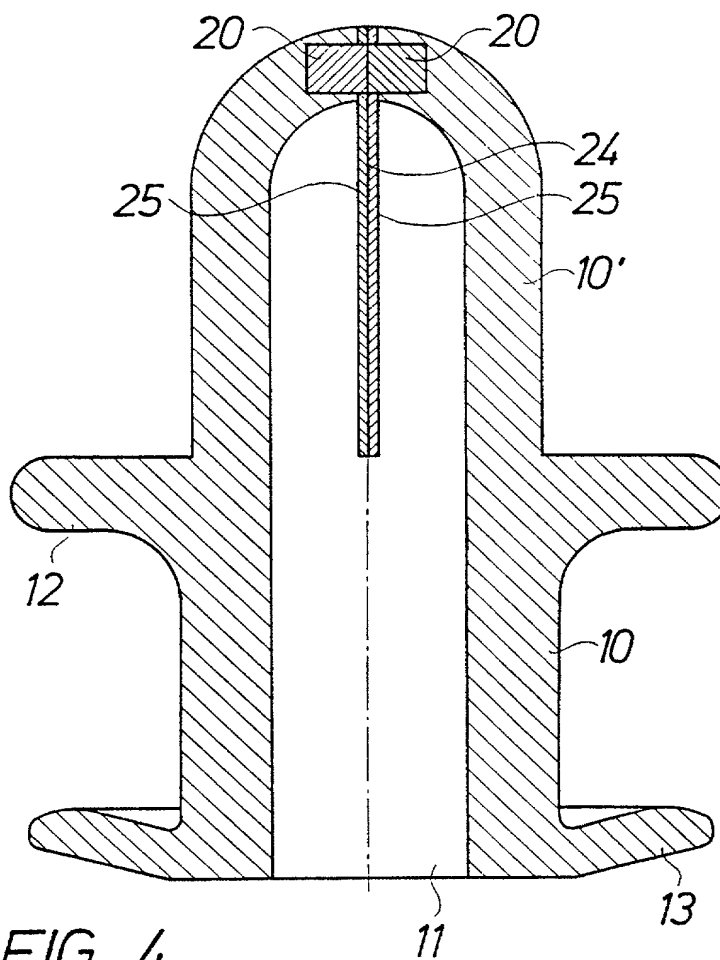


FIG. 4

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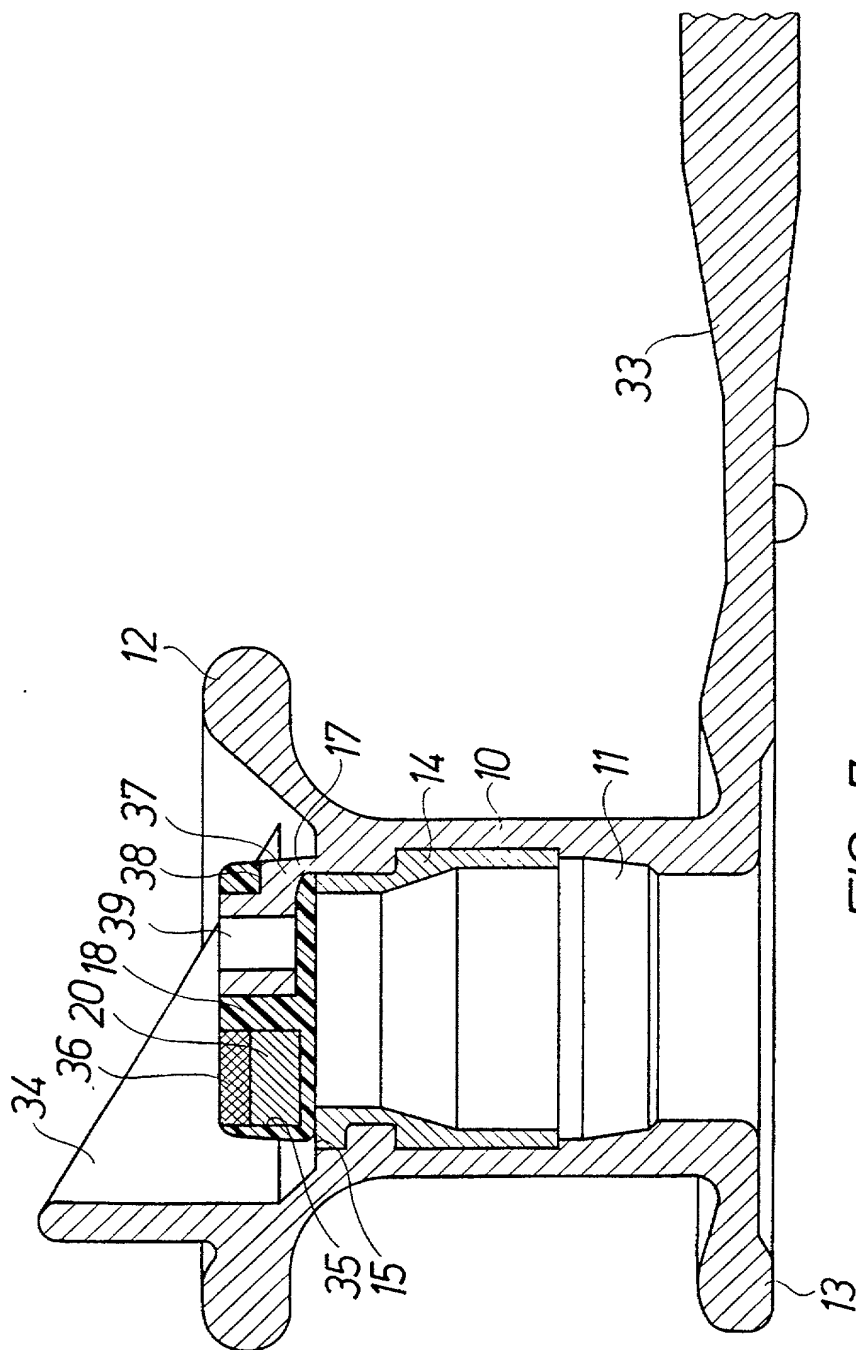


FIG. 7

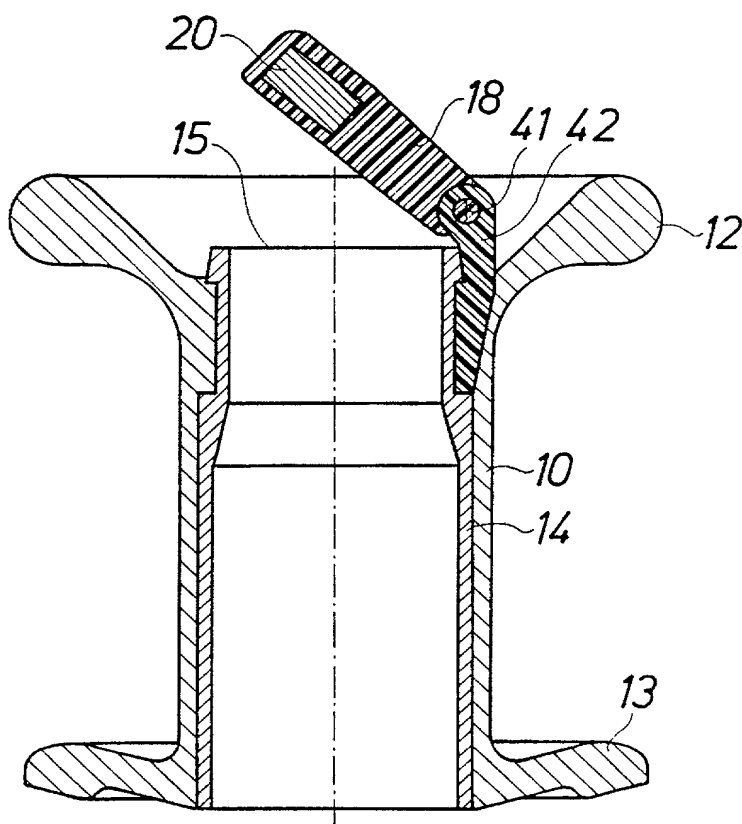


FIG. 8

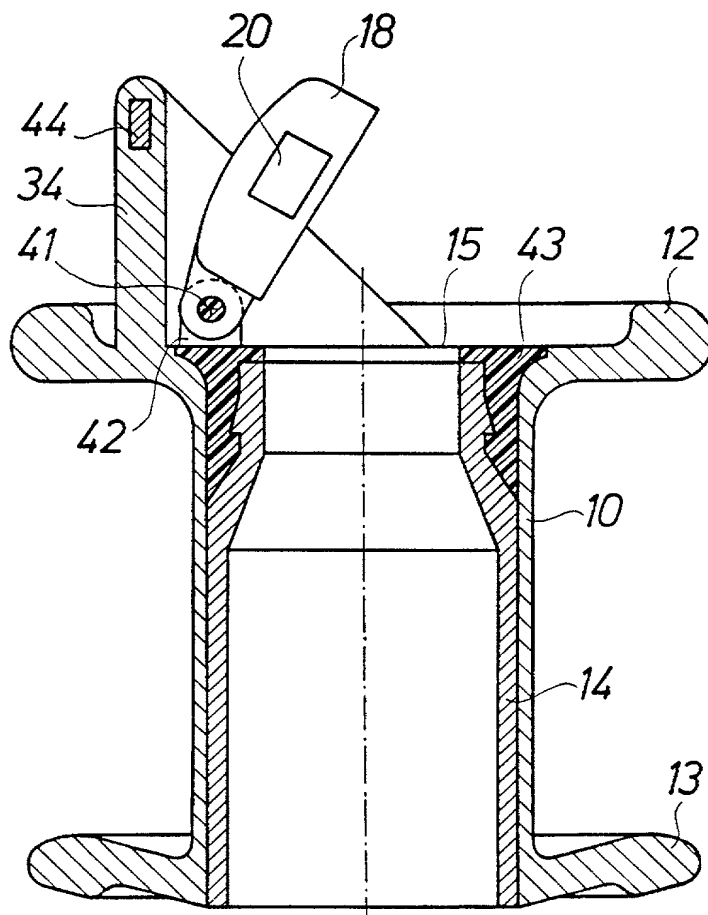
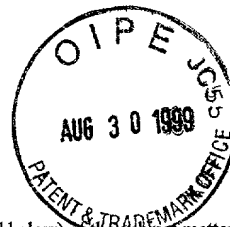


FIG. 9

Declaration For U.S. Patent Application

(PTO/SB/01)



As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled.

VOICE PROSTHESIS

the specification of which (Check one of blocks 1, 2 or 3)

1. ☐ is attached hereto.2. ☒ was filed on 26 May 1997 as International PCT Application Serial No. PCT/SE97/00855
and was amended on _____ (if applicable).3. ☐ was filed on _____ as U.S. Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56

I claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date prior to the application on which priority is claimed

List of Prior Foreign Applications (if applicable)

CERTIFIED COPY ATTACHED?

<u>9601995-5</u> (Application Number)	<u>SWEDEN</u> (Country)	<u>24 May 1996</u> (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
_____ (Application Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____ (Application Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____ (Application Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

☐ Additional foreign application numbers are listed on the attached sheet, PTO/SB/02B - Supplemental Priority Data Sheet or similar sheet

I claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below

List of U.S. Provisional Applications (if applicable)

_____ (Application Number)	_____ (Day/Month/Year Filed)
_____ (Application Number)	_____ (Day/Month/Year Filed)

☐ Additional provisional application numbers are listed on the attached sheet, PTO/SB/02B - Supplemental Priority Data Sheet or similar sheet

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

List of U.S. Parent Application Or PCT Parent Numbers (if applicable)

_____ (Number)	_____ (Day/Month/Year Filed)	_____ (Status: Abandoned; Pending; Patent Number, if applicable)
_____ (Number)	_____ (Day/Month/Year Filed)	_____ (Status: Abandoned; Pending; Patent Number, if applicable)
_____ (Number)	_____ (Day/Month/Year Filed)	_____ (Status: Abandoned; Pending; Patent Number, if applicable)

☐ Additional U.S. or PCT international application numbers are listed on the attached sheet, PTO/SB/02B - Supplemental Priority Data Sheet or similar sheet

